

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:21-CV-7-BO

KATIE FULMORE and)
THOMAS FULMORE,)
Plaintiffs,)
v.)
JOHNSON & JOHNSON and)
ETHICON, INC.)
Defendants.)

ORDER

This cause comes before the Court on defendants' motion for judgment on the pleadings and plaintiffs' motion for leave to file an amended complaint. The appropriate responses and replies have been filed, or the time for doing so has expired, and a hearing was held before the undersigned on January 12, 2022, at Raleigh, North Carolina.¹ In this posture, the matters are ripe for ruling. For the reasons that follow, defendants' motion is granted and plaintiffs' motion is denied.

BACKGROUND

Defendants manufacture pelvic mesh products targeted toward women who suffer from pelvic organ prolapse and/or stress urinary incontinence. These pelvic mesh products contain polypropylene mesh, which plaintiffs allege has been scientifically shown to be biologically incompatible with human tissue and promotes an immune response in a large subset of patients who are implanted with defendants' pelvic mesh products. Immune responses include severe foreign body reactions and chronic inflammatory response. These immune responses in turn can cause chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh which leads

¹ Counsel appeared by videoconference.

to nerve entrapment, chronic infectious response, and chronic pain. Plaintiffs allege the immune response can further cause new-onset of painful sexual relations, significant urinary dysfunction, vaginal shortening, and anatomic deformation.

Plaintiff Katie Fulmore (Mrs. Fulmore) was implanted with defendant Ethicon's Gynecare TVT pelvic mesh product by Dr. Michael Jones at Cape Fear Valley Health System in Fayetteville, North Carolina on March 21, 2005. Subsequent to her surgery, Mrs. Fulmore developed complications, including mesh implant complications which necessitated removal, worsening mixed incontinence, pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, nocturia, urinary tract infections, and urgency. Plaintiffs allege that defendants knew or should have known that their pelvic mesh products unreasonably exposed patients to the risk of serious harm while conferring no benefit over feasible alternatives. Plaintiffs allege that while defendants were aggressively marketing their pelvic mesh products they were aware of the risks and complications their products posed. In April 2019, the Food and Drug Administration ordered all pelvic mesh manufacturers, including defendants, to cease selling and distributing their products after finding that the probable risks did not outweigh the probable benefits.

Plaintiffs commenced this action by filing a complaint against defendants on December 30, 2020. In their complaint, plaintiffs allege claims for negligence; strict liability – design defect; strict liability – manufacturing defect; strict liability – failure to warn; strict liability – defective product; breach of express warranty; breach of implied warranty; fraudulent concealment; constructive fraud; discovery rule, tolling and fraudulent concealment; negligent misrepresentation; negligent infliction of emotional distress; violation of North Carolina's Consumer Protection Act; gross negligence; loss of consortium; unjust enrichment; and punitive damages.

In their motion for judgment on the pleadings, defendants argue that plaintiffs' claims are barred by North Carolina's statute of repose applicable to products liability actions. Defendants further argue that plaintiffs have failed to state a claim upon which relief may be granted. Plaintiffs have not responded to defendants' motion for judgment on the pleadings, but instead have moved for leave to amend their complaint. Plaintiffs contend that their proposed amendment will cure any deficiency identified by defendants. Defendants contend that allowing plaintiffs to amend their complaint would be futile, as their new allegations do not overcome defendants' statute of repose defense.

DISCUSSION

I. Motion for judgment on the pleadings.

A motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) allows a party to move for entry of judgment after the close of the pleadings stage, but early enough so as not to delay trial. Fed. R. Civ. P. 12(c). Courts apply the Rule 12(b)(6) standard when reviewing a motion under Rule 12(c). *Mayfield v. Nat'l Ass'n for Stock Car Auto Racing, Inc.*, 674 F.3d 369, 375 (4th Cir. 2012). “Judgment on the pleadings is not properly granted unless the moving party has clearly established that no material issue of fact remains to be resolved and the party is entitled to judgment as a matter of law.” *United States v. Any & all Radio Station Transmission Equip.*, 207 F.3d 458, 462 (8th Cir. 2000).

Defendants first argue that plaintiffs' claims are barred by North Carolina's statute of repose and the Court agrees. “A statute of repose creates a substantive right in those protected to be free from liability after a legislatively-determined period of time.” *First United Methodist Church of Hyattsville v. U.S. Gypsum Co.*, 882 F.2d 862, 866 (4th Cir. 1989). For products liability actions such as this, North Carolina applies a statute of repose which begins “on the date of initial

purchase for use or consumption.” N.C. Gen. Stat. § 1-46.1(1). Unlike a statute of limitations, a statute of repose “serves as an unyielding and absolute barrier that prevents a plaintiff’s right of action even before his cause of action may accrue, which is generally recognized as the point in time when the elements necessary for a legal wrong coalesce.” *Black v. Littlejohn*, 312 N.C. 626, 633 (1985). North Carolina’s products liability statute of repose thus serves as “a condition precedent to the action itself[,] whereas a statute of limitation acts as a procedural bar to an action which has already accrued.” *Nat'l Prop. Invs., VIII v. Shell Oil Co.*, 950 F. Supp. 710, 713 (E.D.N.C. 1996).

Mrs. Fulmore’s transvaginal mesh implant surgery occurred on March 21, 2005, and is properly considered the date of initial purchase for use or consumption for purposes of the statute of repose. At that time, North Carolina imposed a six-year statute of repose. *See* N.C. Gen. Stat. § 1-50(6); 2009 N.C. Sess. Laws 2009-420 § 3 (amendment enacting a twelve-year statute of repose for products liability actions applies only to claims which accrue on or after October 1, 2009). “All products liability claims, regardless of their nature, are subject to this statute.” *Nat'l Prop. Invs.,* 950 F. Supp. at 713. As plaintiffs did not file suit until December 2020, their claims are plainly barred by the statute of repose.

II. Motion to Amend.

As discussed above, in lieu of responding to the motion for judgment on the pleadings, plaintiffs elected to move to amend their complaint and argue that their amended complaint will render the motion for judgment on the pleadings moot.

Rule 15 of the Federal Rules of Civil Procedure directs that leave to amend be freely given when justice requires. “This liberal rule gives effect to the federal policy in favor of resolving cases on their merits instead of disposing of them on technicalities.” *Laber v. Harvey*, 438 F.3d 404, 426

(4th Cir. 2006) (citations omitted). A court should only deny leave to amend a pleading when the amendment would be prejudicial to the opposing party, where there has been bad faith on the part of the moving party, or when the amendment would be futile. *Johnson v. Oroweat Food Co.*, 785 F.2d 503, 509 (4th Cir. 1986) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)). A proposed amendment is “futile if the claim it presents would not survive a motion to dismiss.” *Save Our Sound OBX, Inc. v. N. Carolina Dep’t of Transp.*, 914 F.3d 213, 228 (4th Cir. 2019) (citation omitted).

Plaintiffs contend that they have pled facts and theories in their proposed amended complaint that toll and/or indicate the initial date the applicable statutes of limitations and repose commenced as relating to all claims asserted, including their warranty-based claims. If permitted to amend their complaint, plaintiffs would allege that defendants made false representations or concealed material facts, that equitable tolling applies to any statute of limitations, that defendants waived or should be equitably estopped from raising the statute of repose because plaintiffs actively pursued resolution of their claims and plaintiffs reasonably relied on defendants’ representations before filing this action, that the date on which the statute of repose begins to run is the same as the date for the accrual of the cause of action under the continuing course of treatment doctrine, and finally that the latent disease exception applies to toll the statute of repose.

[DE 25-1 ¶¶ 68-79].

Plaintiffs argue that equitable estoppel may defeat a defense based upon a statute of repose, citing *Bryant v. Adams*, 116 N.C. App. 448 (1994). The *Adams* court, however, considered whether a defendant could be estopped from raising the statute of repose found in N.C. Gen. Stat. § 1-15(c), but that statute expressly provides that the period of repose “shall not be asserted as a defense by any person who shall have been guilty of fraud . . .” *Id.* § 1-15(e); *see also Goodman v. Holmes*

& McLaurin Att'ys at L., 192 N.C. App. 467, 474 (2008) (distinguishing *Adams* from professional malpractice statute of repose). The products liability repose period includes no such limitation on the defense based on fraud. Plaintiff's reliance on the discovery rule is also inapplicable to the statute of repose, as a statute of repose "begins when a specific event occurs, regardless of whether a cause of action has accrued or whether any injury has resulted." *Black*, 312 N.C. at 633. Moreover, "a statute of repose is typically an absolute time limit beyond which liability no longer exists and is not tolled for any reason because to do so would upset the economic balance struck by the legislative body." *First United Methodist Church of Hyattsville*, 882 F.2d at 866.

Plaintiffs fare no better with their reliance on the continuing course of treatment doctrine or latent disease exception. The continuing course of treatment doctrine applies to professional malpractice claims and can be applied in order to determine when the "last act" occurs to trigger the period of repose for such claims. *See Stallings v. Gunter*, 99 N.C. App. 710, 714 (1990). But for products liability actions, any claim accrues "on the date of initial purchase for use or consumption." N.C. Gen. Stat. § 1-46.1(1). There is thus no need to determine when any "last act" occurs for accrual of the claim, as the triggering date for the statute of repose is fixed on the date of initial purchase.

The latent disease exception is similarly inapplicable. The latent disease exception to the statute of repose applies where "the plaintiff's injury is a disease, (2) it is difficult to establish the exact time of injury (when the disease process started) and (3) it is difficult to establish that the disease was caused by the product." *In re Mentor Corp.*, No. 2004408MD2004CDL, 2016 WL 4385846, at *2 (M.D. Ga. Aug. 15, 2016) (analyzing North Carolina law). While this exception has been held applicable to a products liability action, *Guy v. E.I. DuPont de Nemours & Co.*, 792

F.2d 457, 460 (4th Cir. 1986), Mrs. Fulmore has not alleged that defendants' product caused her to have any disease.

"A true latent disease, such as the asbestosis at issue in *Wilder* [v. *Amatex Corp.*, 314 N.C. 550 (1985)], or the plaintiff's leukemia associated with exposure to toxic discharges over many years in *Stahle v. CTS Corp.*, 817 F.3d 96, 98 (4th Cir. 2016), develops within the body over an extended time period before manifesting any symptoms." *Cramer v. Ethicon, Inc.*, No. 1:20-CV-95-MOC-WCM, 2021 WL 243872, at *5 (W.D.N.C. Jan. 25, 2021). Mrs. Fulmore has alleged that she suffers from what she herself describes as *injuries* such as pelvic pain, dyspareunia, voiding dysfunction, worsening mixed-incontinence, and dysuria. [DE 25-1 ¶ 79]. In other words, Mrs. Fulmore has alleged that she has experienced complications or symptoms from the implantation of pelvic mesh, but she has not alleged that she has developed any disease as that term as been defined in cases applying North Carolina's latent disease exception. *Cramer*, 2021 WL 243872, at *6; *In re Mentor Corp.*, 2016 WL 4385846, at *3.

Finally, plaintiffs rely on defendants' alleged waiver of their limitations and repose defenses based upon Mrs. Fulmore's active pursuit of the resolution of her claims prior to filing suit. *See* [DE 25-1 ¶ 77]. Though there is scant discussion of the alleged waiver or why defendants would be equitably estopped in the proposed amended complaint, this allegation concerns an alleged tolling agreement which was discussed at the hearing. Defendants persuasively argued that any such an agreement would not apply to toll any period for claims already past the period of repose. It is a plaintiff's burden to demonstrate that the statute of repose does not bar her claim, *Robinson v. Bridgestone/Firestone N. Am. Tire, L.L.C.*, 209 N.C. App. 310, 318 (2011), and plaintiffs have not carried their burden in this case.

Accordingly, plaintiffs' proposed amendments fail to bring their claims within the applicable statute of repose and granting leave to amend would therefore be futile. The motion to amend is denied.

CONCLUSION

For the foregoing reasons, defendants' motion for judgment on the pleadings [DE 23] is GRANTED and plaintiffs' motion to amend [DE 25] is DENIED. The clerk is DIRECTED to enter judgment and close the case.

SO ORDERED, this 20 day of January, 2022.

Terrence Boyle
TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE